

1FW/1626

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Scott D. Edmondson, et al



Serial No. 10/560,771

Filed: December 13, 2005

For: CYCLOHEXYLGLYCINE DERIVATIVES AS  
DIPEPTIDYL INHIBITORS FOR THE TREATMENT OR  
PREVENTION OF DIABETESArt Unit: To Be AssignedExaminer: To Be AssignedCommissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK &amp; CO., INC.

By Denise Brown Date 3/9/2006

**INFORMATION DISCLOSURE STATEMENT**

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE
10/540,283	June 20, 2005	21304YP
10/537,476	June 3, 2005	21288YP
10/530,215	April 4, 2005	21239YP
10/542,694	July 19, 2005	21329YP
10/556,805	November 14, 2005	21404P
10/558,931	November 30, 2005	21431P

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

By: Philippe L. Durette

Attorney \_\_\_\_\_ For Applicant(s)

Reg. No. 35,125

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594- 4568

Date: March 9, 2006

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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
	8	PCT	WO 03/082817 A2		MERCK & CO., INC.	10/09/2003
	9	PCT	WO 03/000180 A2		MERCK & CO., INC.	01/03/2003
	10	PCT	WO 03/000181 A2		MERCK & CO., INC.	01/03/2003
	11	PCT	WO 03/000181 A3		MERCK & CO., INC.	01/03/2003
	12	PCT	WO 02/076450 A1		MERCK & CO., INC.	10/03/2002
	13	PCT	WO 2004/007468 A1		MERCK & CO., INC.	01/22/2004
	14	PCT	WO 2004/032836 A2		MERCK & CO., INC.	04/22/2004
	15	PCT	WO 2004/050022 A2		MERCK & CO., INC.	06/17/2004
	16	PCT	WO 2004/058266 A1		MERCK & CO., INC.	07/15/2004
	17	PCT	WO 2004/064778 A2		MERCK & CO., INC.	08/05/2004

Examiner Signature		Date Considered	
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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

## STATEMENT BY APPLICANT

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Sheet

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of

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**Application Number**

10/560,771

**Filing Date**

December 13, 2005

**First Named Inventor**

Scott D. Edmondson, et al.

## Group Art Unit

Examiner Name

Attorney Docket Number

21443P

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Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
	18	PCT	WO 2004/069162 A2		MERCK & CO., INC.	08/19/2004
	19	PCT	WO 02/02560 A2		NOVO NORDISK A/S	01/10/2002
	20	PCT	WO 01/96295 A2		NOVARTIS AG	12/20/2001
	21	PCT	WO 01/96295 A3		NOVARTIS AG	12/20/2001
	22	PCT	WO 01/34594 A1		Guilford Pharmaceuticals, Inc.	05/17/2001
	23	PCT	WO 00/34241		NOVARTIS AG	06/15/2000
	24	PCT	WO 98/19998 A2		NOVARTIS AG	05/14/1998
	25	PCT	WO 98/19998 A3		NOVARTIS AG	05/14/1998
	26	PCT	WO 97/40832		Hansknoll-Institut Fur Naturstoff-Forschung E.V.	11/06/1997
	27	PCT	WO 03/000180 A3		MERCK & CO., INC.	01/03/2003

**Examiner  
Signature**

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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
	28	PCT	WO 02/02560	A3	NOVO NORDISK	01/10/2002
	29	PCT	WO 01/42262		AKZO NOBEL N.V.	06/14/2001
	30	PCT	WO 2004/043940		MERCK & CO., INC.	05/27/2004
	31	PCT	WO 2004/007468		MERCK & CO., INC.	01/22/2004
	32	PCT	WO 2004/110436		MERCK & CO., INC.	12/23/2004
	33	PCT	WO 2004/112701	A2	MERCK & CO., INC.	12/29/2004
	34	PCT	WO 2004/112701	A3	MERCK & CO., INC.	12/29/2004
	35	PCT	WO 2005/011581	A2	MERCK & CO., INC.	02/10/2005
	36	PCT	WO 2005/044195	A2	MERCK & CO., INC.	05/19/2005
	37	PCT	WO 2005/002530	A2	SMITHKLINE BEECHAM CORP.	01/09/2003

Examiner Signature		Date Considered	
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Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE

**STATEMENT BY APPLICANT**

MAR 13 2006

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Sheet

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of

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**COMPLETE IF KNOWN****Application Number**

10/560,771

**Filing Date**

December 13, 2005

**First Named Inventor**

Scott D. Edmondson, et al.

## Group Art Unit

Examiner Name

Attorney Docket Number

21443P

## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

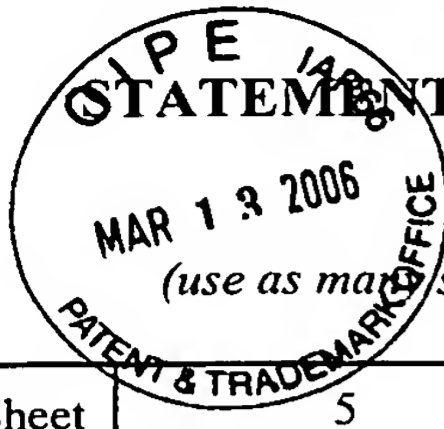
Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
	38	PCT	WO 2005/056003	A1	GRAFFINITY PHARMACEUTICALS AG	06/23/2005
	39	PCT	WO 2005/056013	A1	GRAFFINITY PHARMACEUTICALS AG	06/23/2005
	40	PCT	WO 2005/108382	A1	MERCK & CO., INC.	11/17/2005
	41	PCT	WO2005/116029	A1	MERCK & CO., INC.	12/08/2005
	42	PCT	WO 2005/123685	A1	ASTRAZENECA AB	12/29/2005

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Signature**

Date  
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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE</b>  STATEMENT BY APPLICANT (use as many sheets as necessary)			<b>COMPLETE IF KNOWN</b>		
			Application Number	10/560,771	
			Filing Date	December 13, 2005	
			First Named Inventor	Scott D. Edmondson, et al.	
			Group Art Unit		
			Examiner Name		
Sheet	5	of	5	Attorney Docket Number	21443P

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	43	J. J. Holst, "Treatment of Type 2 Diabetes Mellitus with Agonists of the GLP-1 Receptor or DPP-IV Inhibitors", Expert Opin. Emerg. Drugs, Vol. 9(1) pp. 155-166(2004).
	44	C. F. Deacon, et al., "Inhibitors of dipeptidyl peptidase IV: A Novel Approach for the Prevention and Treatment of Type 2 Diabetes?", Expert Opin. Investig. Drugs, Vol. 13(9) pp. 1091-1102( 2004).
	45	K. Augustyns et al., " Dipeptidyl Peptidase IV Inhibitors as New Therapeutic Agents for the Treatment of Type 2 Diabetes", Expert Opin. Ther. Patents, Vol. 13(4), pp. 499-510(2003).
	46	Novartis AG: WO0034241, "Novel N-substituted-2-Cyanopyrrolidines as Potent Inhibitors of Dipeptidyl Peptidase IV in the Treatment of Non-Insulin-Dependent Diabetes Mellitus", Exp. Opin. Ther. Patents, Vol. 10(12), pp. 1937-1942 (2000).
	47	O. J. Orucker, "Therapeutic potential of dipeptidyl peptidase IV inhibitors for the treatment of type 2 diabetes", Exp. Opin Invest. Drugs, Vol.12, pp. 87-100 (2004).
	48	T. P. Vahl & D. A. D'Alessio, "Gut peptides in the treatment of diabetes mellitus" Exp. Opin. Invest. Drugs, Vol. 13, pp. 177-188 (2004).
	49	L. B. Knudsen, "Glucagon-like peptide-1: The Basis of a New Class of Treatment for Type 2 Diabetes", J. Med. Chem, Vol. 47, pp. 4128-4134 (2004).
	50	A. E. Weber, "Dipeptidyl Peptidase IV Inhibitors for the Treatment of Diabetes", J. Med. Chem, Vol. 47, pp. 4135-4141 (2004).
	51	J. J. Holst and C. F. Deacon, "Glucagon-like peptide 1 and inhibitors of dipeptidyl peptidase IV in the treatment of type 2 diabetes mellitus", Curr. Opin Pharmacology, Vol. 4, pp. 589-596 (2004).
	52	C. F. Deacon, "Perspectives in Diabetes - Therapeutic Strategies Based on Glucagon-Like Peptide 1", Diabetes, Vol. 53, pp. 2181-2189 (2004).
	53	K. Augustyns, et al., "Inhibitors of proline-specific dipeptidyl peptidase: DPP IV inhibitors as a novel approach for the treatment of Type 2 diabetes", Expert Opin. Ther. Patents, Vol. 15(10), pp. 1387-1407 (2005).
	54	Hans-Ulrich Demuth, et al., " Type 2 diabetes - Therapy with dipetidyl peptidase IV inhibitors", Biochimica et Biophysica Acta, Vol. 1751, pp., 33-44 (2005).

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